UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

ADOLOR CORPORATION,	Case No.
Plaintiff, vs. BRUCE A. PEACOCK, MICHAEL R. DOUGHERTY, DAVID JACKSON, PAUL GODDARD, CLAUDE H. NASH, DONALD NICKELSON, ARMANDO ANIDO, GEORGE V. HAGER, JR., DAVID M. MADDEN AND ROBERT T. NELSEN,	VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTY, ABUSE OF CONTROL, GROSS MISMANAGEMENT, WASTE OF CORPORATE ASSETS AND UNJUST ENRICHMENT
Defendants,	
- and -	
ADOLOR CORPORATION, a Delaware corporation,	
Nominal Defendant.)	DEMAND FOR JURY TRIAL

Plaintiff, by his attorneys, submits this Verified Shareholder Derivative Complaint (the "Complaint") against the defendants named herein.

NATURE OF THE ACTION

1. This is a shareholder derivative action brought by a shareholder of Adolor Corporation ("Adolor" or the "Company") on behalf of the Company against certain of its officers and directors seeking to remedy defendants' violations of Pennsylvania Law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate asset, and unjust enrichment that occurred between September 2003 and the Present (the "Relevant Period") and that have caused substantial losses to Adolor and other damages, such as to its reputation and goodwill.

JURISDICTION AND VENUE

- 2. This Court has jurisdiction over all claims asserted herein pursuant to 28 U.S.C. §1332(a)(2), because complete diversity exists between the plaintiff and each defendant, and the amount in controversy exceeds \$75,000. This action is not a collusive one to confer jurisdiction on this Court it would not otherwise have.
- 3. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this County, or is an individual who has sufficient minimum contacts with Pennsylvania so as to render the exercise of jurisdiction by the Pennsylvania courts permissible under traditional notions of fair play and substantial justice.
- 4. Venue is proper in this Court because one or more of the defendants either resides in or maintains executive offices in this District, a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein and aiding and abetting and conspiracy in violation of fiduciary duties owed to Adolor occurred in this District, and defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

SUMMARY OF THE ACTION

- 5. Adolor is a development stage biopharmaceutical corporation that discovers, develops and plans to commercialize products to relieve pain while reducing the side effects of currently marketed narcotics. Adolor claims that over 100 million patients experience acute or chronic pain annually in the United States, an occurrence that creates a "large window of opportunity" for more effective analgesics with fewer side effects. Adolor believes that its product candidates, of which EnteregTM (alvimopan) is key, address commercial opportunities in several market segments of more than \$1 billion each. The fortunes of the Company are inextricably tied to successful commercialization of these analgesic indications.
- 6. Adolor's flagship product candidate is EnteregTM. EnteregTM is currently in Phase III clinical trials for the management of postoperative "ileus." Ileus is a temporary impairment of spontaneous movement through the gastrointestinal tract after abdominal or other surgeries, including, but not limited to, simple hysterectomy, radical abdominal hysterectomy and bowel resection. The Company claimed that three Phase III clinical studies, study trials 302, 313 and 308, represented the key clinical efficacy studies necessary to support filing of a new drug application ("NDA") at 6 mg and 12 mg dosage levels for the postoperative ileus indication. Defendants claimed that they would file an NDA for this indication late in the first half of 2004.
- 7. On or before September 23, 2003, the defendants became aware of remarkable and alarming relationships amongst and between the results for the completed 313 and 302 clinical studies. Despite these alarming relationships, defendants focused instead on making a highly positive, encouraging and well received conference call, on September 23, 2003, to discuss results for the most recently completed 313 study.
- 8. During the conference call on September 23, 2003, defendants were asked in various different ways to explain how the differences in the patient subgroups included in the 302 and 313 studies were or could have been related to the remarkable and alarming differences in results between the studies. Surprisingly, the defendants refused to concede any such connection. Instead,

defendants sought alternative explanations and made evasive responses, of a false and misleading nature, such as: (i) insufficient numbers of patients necessary to power the 302 study and achieve statistically significant results; (ii) a clearly stated unwillingness to make head-to-head comparisons between the 302 and 313 studies, to compare and contrast efficacy results by patient subgroup, between the individual studies or as pooled results from both studies; (iii) describing the patient dropout rates for the 302 and 313 studies without explaining how differences in the patient subgroups included in the studies influenced the overall dropout rates; and (iv) stating an "uncertain disbelief" in the confounding impact of the differences in the patient subgroups included in the 302 and 313 study results when questioned directly. The evasive responses of the defendants served to allay concerns within the investment community about the inadequacies of the existing study results and the potential problems, going forward, with the 308 study

- 9. Then, on January 13, 2004, the Company reported shocking news about the 308 study, the third in the series of Phase III clinical trials for the NDA submission. Problems with the 308 study built upon the concealed problems with the 302 study, resulting in failure to demonstrate statistically significant results for the primary endpoint, this time at both dosage levels. Based on the disclosures made in defendants' conference call of January 13, 2004, the price of Adolor's stock plunged 37%, trading as low as \$13.73 per share, on an unprecedented volume of 12.7 million shares.
- 10. The true facts, which were known by each of the defendants but concealed from the investing public during the Relevant Period, were as follows:
- (a) The clinical trial failure in the Entereg[™] Phase III 302 study for postoperative ileus was directly related to objective failure of the therapy in certain patient subgroups, particularly those patients treated for simple hysterectomy;
- (b) Additional Entereg[™] Phase III clinical trials composed of patient subgroups similar to the 302 study would risk repetition of the same therapy failures;

- (c) The 302 study failure at the 12 mg dosage was due to therapy failures in certain patient subgroups, particularly those patients treated for simple hysterectomy, and not "limited power" or insufficient numbers of patients in the study as defendants claimed;
- (d) Despite representations to the contrary, defendants were in a position to make meaningful comparisons for the data and results between patient subgroups, for the 302 and 313 studies, from the very beginning of the Relevant Period;
- (e) Despite defendants' expressions of disbelief at suggestions by analysts that distinctly different results for certain patient subgroups had somehow impacted the quality of results for the 302 and 313 clinical studies, defendants were fully aware of these differences and that the clinical program was indeed adversely impacted from the very beginning of the Relevant Period;
- (f) The Entereg[™] Phase III 313 clinical study met the primary efficacy endpoint, at both dosage levels, because it excluded certain patient subgroups already known by defendants prior to the Relevant Period to produce disappointing results for the treatment of postoperative ileus;
- (g) The Entereg[™] Phase III 308 prospective study was at great risk of failing to achieve statistically significant results for the primary efficacy endpoint, at both dosage levels, because it would include a large number of certain patient subgroups already known to produce disappointing results for the treatment of postoperative ileus;
- (h) Elimination of certain patient subgroups already known to produce disappointing results for the treatment of postoperative ileus from the 313 study created an opportunity to present highly encouraging clinical results to the investment community at the very beginning of the Relevant Period, while deferring the prospect of disappointing results from the prospective 308 study; and
- (i) Since the Entereg[™] Phase III pivotal studies were designed to study two different dosages across a number of patient subgroups in three separate trials, defendants were aware, from the very beginning of the Relevant Period, that the mixed results within the patient subgroups for the 302 and 313 studies confounded the results, making it difficult for the Food and

Drug Administration ("FDA") to approve an EnteregTM NDA based on the prospect of disappointing results from the prospective 308 study.

11. As a result of the defendants' false statements, Adolor's stock price traded at inflated prices during the Relevant Period, causing millions of dollars of damages to the Company. On November 12, 2003, as shares traded at prices as high as \$18.14, the defendants caused the Company to sell 6,900,000 shares of its common stock for gross proceeds of approximately \$119 million.

THE PARTIES

- 12. Plaintiff James Wilson is, a resident of the State of Texas, is and was at times relevant hereto, an owner and holder of Adolor common stock.
- 13. Nominal defendant Adolor is a corporation organized and existing under the laws of the state of Delaware with its headquarters located at 700 Pennsylvania Drive, Exton, Pennsylvania 19341. Adolor is a development stage biopharmaceutical corporation that discovers, develops and plans to commercialize products to relieve pain while reducing the side effects of currently marketed narcotics. Adolor claims that over 100 million patients experience acute or chronic pain annually in the United States, an occurrence that creates a "large window of opportunity" for more effective analgesics with fewer side effects. Adolor believes that its product candidates, of which EnteregTM is key, address commercial opportunities in several market segments of more than \$1 billion each. The fortunes of the Company are inextricably tied to successful commercialization of these analgesic indications.
- 14. Defendant Bruce A. Peacock ("Peacock") is, and at all times relevant hereto was, President, Chief Executive Officer ("CEO") and a director of Adolor. Because of Peacock's positions, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and Board of Directors' (the "Board") meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period,

Peacock participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and Securities and Exchange Commission ("SEC") filings. For FY:03, Adolor paid defendant Peacock \$536,202, in salary, bonus and other compensation, and granted him 150,000 options to purchase Adolor stock. Peacock is a resident of Pennsylvania.

- 15. Defendant Michael R. Dougherty ("Dougherty") is, and at all times relevant hereto was, Senior Vice President, Chief Operating Officer, Chief Financial Officer and Treasurer of Adolor. Because of Dougherty's positions, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management meetings and via reports and other information provided to him in connection therewith. During the Relevant Period, Dougherty participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. For FY:03, Adolor paid defendant Dougherty \$356,500, in salary, bonus and other compensation, and granted him 25,000 options to purchase Adolor stock. Dougherty is a resident of Pennsylvania.
- 16. Defendant David Jackson ("Jackson") is, and at all times relevant hereto was, Senior Vice President of Research and Development of Adolor. Because of Jackson's position, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management meetings and via reports and other information provided to him in connection therewith. During the Relevant Period, Jackson participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. For FY:03, Adolor paid defendant Jackson \$414,336, in salary, bonus and other compensation, and granted him 43,200 options to purchase Adolor stock. Jackson is a resident of Pennsylvania.

- 17. Defendant Paul Goddard ("Goddard") is, and at all times relevant hereto was, a director of Adolor. Because of Goddard's position, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Goddard participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Goddard is a resident of California.
- 18. Defendant Claude H. Nash ("Nash") is, and at all times relevant hereto was, a director of Adolor. Because of Nash's position, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Nash participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Nash is a resident of Pennsylvania.
- 19. Defendant Donald Nickelson ("Nickelson") is, and at all times relevant hereto was, a director of Adolor. Because of Nickelson's position, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Nickelson participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Nickelson is a resident of Florida.

- 20. Defendant Armando Anido ("Anido") is, and at all times relevant hereto was, a director of Adolor. Because of Anido's position, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Anido participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Anido is a resident of Maryland.
- 21. Defendant George V. Hager, Jr. ("Hager") is, and at all times relevant hereto was, a director of Adolor. Because of Hager's position, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Hager participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Hager is a resident of New Jersey.
- 22. Defendant David M. Madden ("Madden") is, and at all times relevant hereto was, a director of Adolor. Because of Madden's position, he knew the adverse non-public information about the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Madden participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Madden is a resident of New York.
- 23. Defendant Robert T. Nelsen ("Nelsen") is, and at all times relevant hereto was, a director of Adolor. Because of Nelsen's position, he knew the adverse non-public information about

the business of Adolor, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Nelsen participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. During the Relevant Period, Nelsen sold 22,000 shares of Adolor stock for proceeds of \$420,420. Nelsen is a resident of Minnesota.

24. The defendants identified in ¶¶14, 17-23 are referred to herein as the "Director Defendants." The defendants identified in ¶¶14-16 are referred to herein as the "Officer Defendants." The defendant identified in ¶23 is referred to herein as the "Insider Selling Defendant." Collectively, the Director Defendants, the Officer Defendants and the Insider Selling Defendant are referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

- 25. By reason of their positions as officers, directors and/or fiduciaries of Adolor and because of their ability to control the business and corporate affairs of Adolor, the Individual Defendants owed Adolor and its shareholders fiduciary obligations of trust, loyalty, good faith and due care, and were and are required to use their utmost ability to control and manage Adolor in a fair, just, honest and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Adolor and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.
- 26. Each director and officer of the Company owes to Adolor and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with regard to the

Company's revenue, margins, operations, performance, management, projections and forecasts so that the market price of the Company's stock would be based on truthful and accurate information.

- 27. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Adolor, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Because of their advisory, executive, managerial and directorial positions with Adolor, each of the Individual Defendants had access to adverse non-public information about the financial condition, operations, and improper representations of Adolor.
- 28. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Adolor, and was at all times acting within the course and scope of such agency.
- 29. To discharge their duties, the officers and directors of Adolor were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Adolor were required to, among other things:
- (a) refrain from acting upon material inside corporate information to benefit themselves;
- (b) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;
- (c) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
- (d) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's financial results and prospects, and ensuring that the Company maintained an adequate

system of financial controls such that the Company's financial reporting would be true and accurate at all times;

- (e) remain informed as to how Adolor conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and
- (f) ensure that the Company was operated in a diligent, honest and prudent manner in compliance with all applicable federal, state and local laws, rules and regulations.
- 30. Each Individual Defendant, by virtue of his or her position as a director and/or officer, wed to the Company and to its shareholders the fiduciary duties of loyalty, good faith and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Adolor, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also officers and/or directors of the Company during the Relevant Period has been ratified by the remaining Individual Defendants who collectively comprised all of Adolor's Board during the Relevant Period.
- 31. The Individual Defendants breached their duties of loyalty and good faith by allowing defendants to cause or by themselves causing the Company to misrepresent its financial results and prospects, as detailed herein *infra*, and by failing to prevent the Individual Defendants from taking such illegal actions. In addition, as a result of defendants' illegal actions and course of conduct during the Relevant Period, the Company is now the subject of several class action law suits that allege violations of federal securities laws. As a result, Adolor has expended and will ontinue to expend significant sums of money. Such expenditures include, but are not limited to:

- (a) Costs incurred to carry out internal investigations, including legal fees paid to outside counsel;
- (b) Costs incurred in investigating and defending Adolor and certain officers in the class actions, plus potentially millions of dollars in settlements or to satisfy an adverse judgment.
- 32. Moreover, these actions have irreparably damaged Adolor's corporate image and goodwill. For at least the foreseeable future, Adolor will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Adolor's ability to raise equity capital or debt on favorable terms in the future is now impaired.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

- 33. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breach of their respective duties.
- 34. During all times relevant hereto, the Individual Defendants collectively and individually initiated a course of conduct that was designed to and did: (i) conceal the fact that the Company was improperly misrepresenting its financial results, in order to allow defendants to artificially inflate the price of the Company's shares; (ii) maintain the Individual Defendants' executive and directorial positions at Adolor and the profits, power and prestige that the Individual Defendants enjoyed as a result of these positions; and (iii) deceive the investing public, including shareholders of Adolor, regarding the Individual Defendants' management of Adolor's operations, the Company's financial health and stability, and future business prospects, specifically related to the Company's financials that had been misrepresented by defendants throughout the Relevant Period. In furtherance of this plan, conspiracy and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein.

- 35. The Individual Defendants engaged in a conspiracy, common enterprise and/or common course of conduct commencing by at least September 2003 and continuing thereafter. During this time the Individual Defendants caused the Company to conceal the true fact that Adolor was misrepresenting its financial results. In addition, defendants also made other specific, false statements about Adolor's financial performance and future business prospects, as alleged herein.
- 36. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment; to conceal adverse information concerning the Company's operations, financial condition and future business prospects; and to artificially inflate the price of Adolor common stock so they could: (i) dispose of \$420,420 of their personally held stock; and (ii) protect and enhance their executive and directorial positions and the substantial compensation and prestige they obtained as a result thereof.
- 37. The Individual Defendants accomplished their conspiracy, common enterprise and/or common course of conduct by causing the Company to purposefully, recklessly or negligently misrepresent its financial results. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary and substantial participant in the conspiracy, common enterprise and/or common course of conduct complained of herein.
- 38. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing

BACKGROUND

39. Adolor is a development stage biopharmaceutical corporation that discovers, develops and plans to commercialize products to relieve pain while reducing the side effects of currently

marketed narcotics. Adolor claimed that over 100 million patients experience acute or chronic pain annually in the United States, an occurrence that creates a "large window of opportunity" for more effective analgesics with fewer side effects. Adolor claimed that its product candidates, of which EnteregTM is key, address commercial opportunities in several market segments of more than \$1 billion each. The fortunes of the Company are inextricably tied to successful commercialization of these analgesic indications.

- 40. Adolor's flagship product candidate is Entereg[™]. Entereg[™] is currently in Phase III clinical trials for the management of postoperative ileus. Ileus is a temporary impairment of spontaneous movement through the gastrointestinal tract after abdominal or other surgeries, including, but not limited to simple hysterectomy, radical abdominal hysterectomy and bowel resection. On September 23, 2003, defendants stated that they planned to file an NDA for this indication late in the first half of 2004.
- 41. The CAS registry number for the dehydrate form of alvimopan is 170098-38-1. The chemical name for alvimopan is [03R-[1(S*),3x,4x]]-N-[2-[[4-3-hydroxyphenyl)-3, 4-dimethyl-1-piperidinyl]methyl]-1-oxo-3-phenylpropyl] glycine.
- 42. The U.S. Centers for Disease Control and Prevention ("CDC") reported in 1997 that nearly 600,000 hysterectomies are performed each year in the United States alone. During the period from 1980 to 1993, nearly 8.5 million women underwent simple hysterectomies. Nearly a quarter of these procedures were performed using a vaginal surgical method, while the rest were performed as abdominal surgeries.
- 43. The American Cancer Society reports that hospital stays for simple hysterectomies are relatively short, in the range of one to two days for vaginal procedures and three to five days for abdominal procedures, versus radical hysterectomies requiring hospital stays in the range of five to seven days. The National Institutes of Health reports that hospital stays for bowel resection surgery are in the range of five to seven days.

- 44. Adolor had licensed alvimopan in April 2002 to GlaxoSmithKline ("GSK"), the Company's joint venture partner. The Company received a \$50 million non-refundable licensing fee from GSK and proclaimed it would receive as much as \$220 million in additional milestone and other payments, based on Company achievement of regulatory objectives for the development and commercialization of the drug.
- 45. In August of 2002, the Company defined a clinical program to test EnteregTM, at the 6 mg and 12 mg dosage levels, in three separate Phase III clinical studies, designated as prospective study trials 302, 308 and 313. The Company claimed that these three clinical trials represented the clinical efficacy studies they would file a NDA. Not surprisingly, the Company planned to enroll a variety of patient subgroups, including patients having undergone simple hysterectomy, radical abdominal hysterectomy and bowel resection.
- 46. On April 2, 2003, the Individual Defendants caused the Company to report results for the 302 study and issued a press release entitled "Adolor Announces Top-Line Results of Alvimopan Phase 3 Clinical Study." The press release stated in relevant part:

Adolor Corporation announced today top-line results of its first Phase 3 clinical study (14CL302) for its novel product candidate, alvimopan, in the management of postoperative ileus ("POI").

A statistically significant difference was achieved in the primary endpoint of the study, time to recovery of gastrointestinal function, in patients in the alvimopan 6 mg treatment group compared to patients in the placebo group (Cox proportional hazard model; hazard ratio = 1.47; P(less than)0.01). Time to recovery of gastrointestinal function was a composite measure of the time to recovery of both lower and upper gastrointestinal function as defined by time to first flatus or first bowel movement and time to tolerability of solid foods, whichever occurred last. A difference in favor of the alvimopan 6 mg treatment group versus placebo was observed for all secondary endpoints, including time to hospital discharge order written. A positive trend was observed in the primary endpoint of the study for the alvimopan 12 mg treatment group; however, the difference from placebo was not statistically significant (Cox proportional hazard model, hazard ratio = 1.23; P = 0.11).

Alvimopan was generally well tolerated in this study. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and hypotension.

47. The April 2, 2003 press release reported the completion and results of the 302 study and revised guidance to target the filing of an NDA by the end of calendar year 2003. The report of the results for the 302 study was, at best, inexplicable and confusing, since a statistically significant result was achieved at the 6 mg dosage level, while the 12 mg dosage level failed to achieve a statistically significant result for the primary endpoint, the time to recovery of spontaneous movement through the gastrointestinal tract.

IMPROPER STATEMENTS

48. On September 23, 2003, the Individual Defendants caused the Company to issue a press release reporting both the completion of the 313 study and revised guidance, targeting the filing of an NDA by late in the first half of 2004, entitled "Adolor Corporation Announces Positive Top-Line Results in 2nd Phase 3 Study of Alvimopan in Postoperative Ileus; Primary Endpoint Statistically Significant in 6 mg and 12 mg Doses." The press release stated in relevant part:

Adolor Corporation announced today top-line results of its second Phase 3 clinical study (14CL313) of EnteregTM (alvimopan) in the management of postoperative ileus (POI). A statistically significant difference was achieved in the primary endpoint of the study, time to recovery of gastrointestinal function, in the EnteregTM (alvimopan) 6 mg and 12 mg treatment groups when each is compared to the placebo group.

"We are very excited to report today's positive results in both the 6 mg and 12 mg treatment groups, and believe they support our goal of submitting a New Drug Application for EnteregTM (alvimopan) to the U.S. Food and Drug Administration late in the first half of 2004," stated Bruce A. Peacock, president and chief executive officer of Adolor. "Successful completion of Study 313 is an important accomplishment in our clinical development program evaluating EnteregTM (alvimopan) in the management of postoperative ileus and builds on the top-line results from Study 302 announced in April of this year. We are now focused on completing Study 308 as our next important milestone. We believe our four phase 3 clinical studies represent a very substantial clinical development program which, when complete, will have enrolled approximately 2,000 patients."

In the primary endpoint of Study 313, time to recovery of gastrointestinal function, a statistically significant difference was achieved in both the EnteregTM (alvimopan) 6 mg and 12 mg treatment groups, each as compared to the placebo group (Cox proportional hazard model; for 6 mg group, hazard ratio = 1.28; P less than 0.05; for 12 mg group, hazard ratio = 1.54; P less than 0.01). Mean times of recovery were 120 hours, 105 hours, and 98 hours for the placebo, 6 mg, and 12 mg groups, respectively. This equates to mean times to recovery of gastrointestinal function that are approximately 15 hours and 22 hours sooner for the alvimopan 6 mg and 12 mg treatment groups, respectively, each as compared with placebo.

A difference in favor of EnteregTM (alvimopan) was observed for all of the secondary endpoints in both the 6 mg and 12 mg treatment groups, including a difference in time to hospital discharge order written in the 6 mg treatment group (Cox proportional hazard model; hazard ratio = 1.25) and a statistically significant difference in the 12 mg treatment group (Cox proportional hazard model; hazard ratio = 1.42). Mean times to hospital discharge order written were approximately 13 hours and 20 hours sooner for the 6 mg and 12 mg treatment groups, respectively, each as compared to placebo.

EnteregTM (alvimopan) was generally well tolerated in this study. The most frequently observed adverse events in both the 6 mg and 12 mg treatment groups and the placebo groups were nausea, vomiting, and hypotension.

- 49. Contrary to the purported statistical significance and so-called "positive" results, defendants were well aware of the remarkable and alarming differences between the just completed 313 study and the earlier 302 study. Despite these alarming differences, the defendants were focused on making a highly positive and encouraging disclosure of results for the 313 study.
- 50. On September 23, 2003, defendants Dougherty, Peacock and Jackson held a conference call where defendants announced the results for the 313 study and reported results that were *remarkably better than those reported for the 302 study*, particularly at the 12 mg dosage level. In fact, the defendants knew of and at least partially disclosed the differences that existed between the 302 and 313 study patient populations during the September 23, 2003 conference call. During the call, defendants remarked:

As compared to Study 302, the results of which we reported earlier this year, this study did not enroll simple hysterectomy patients, which you may recall were included in Study 302, but did enroll a small number of patients undergoing bowel resection, which were not enrolled in Study 302.

51. During September 23, 2003, the defendants also disclosed that the prospective 308 study would look at a patient population *similar* to that in the 302 study, including enrollment of simple hysterectomy patients, not to exceed 20% of all patients. During the call, defendant Jackson remarked:

Study 308[] is similar in design to both studies 302 and 313. Patients are randomized to placebo, 6 mg or 12 mg Alvimopan treatment group. Study 308 will enroll approximately 660 patients undergoing small bowel resection, simple or radical hysterectomy. In Study 308, similar to study 302, simple hysterectomies will not exceed 20% of total enrollment.

- 52. The partial disclosures made during the September 23, 2003 conference call for study 313 failed to address that: (i) where the 302 study had failed, whether the decision to exclude simple hysterectomy patients and include bowel resection patients was in fact responsible for achievement of statistically significant results at the 12 mg dosage level; and (ii) how adding back both simple hysterectomy and bowel resection patients would impact results for the prospective study 308.
- 53. The implications of the different patient subpopulations in the 313 and 302 studies, coupled with the disparate results at the 12 mg level, were not lost on the analysts participating in the September 23, 2003 conference call. Defendants were asked in various different ways to explain how the disparate composition of patient subgroups in the 302 and 313 studies were or could have been related to the remarkable and alarming differences in results between the studies. Surprisingly, the defendants refused to concede any such connection. Instead, defendants sought alternative and evasive explanations, of a false and misleading nature, such as "study powering," an insufficient number of patients necessary to achieve statistically significant results in the 302 study. During the conference call, defendant Peacock answered the following question asked by Patrick Flannigan, an analyst for Adams, Harkness and Hill:

[Flannigan:] Hey, guys, and congratulations on a pretty solid data set. I was just wondering on that dose response comment, can you kind of comment a little about why we're seeing a dose response in this particular study and let's say in the first Phase 3 study we did not? *Should we expect to see a dose response with these two doses?*

[Peacock:] Well, let's go back to the first study, Patrick, as a place to start. And of course, we saw statistically significant result [sic] in six in that study with twelve of the supporting trend. *And here, of course, we see significance in 313 in both doses*.

As we've previously indicated, we believe that both six and twelve have the opportunity to show significance, and we've seen that in these two studies. What we've indicated before in 302 was that we felt that if we up the study - enrolled more patients, we would give 12 a better opportunity to demonstrate the fact, and that's what we've seen in 313.

54. In fact, study 302 had failed to achieve a statistically significant result for the 12 mg dose against the primary endpoint. Defendant Peacock knowingly concealed the fact that the distinctly different patient subgroups studied in study 313, versus study 302 had impacted the results.

Rather than concede that the different patient subgroups appeared to have responded differently to the drug, defendant Peacock concealed the true reasons for the 302 study failure.

55. Also, during the September 23, 2003 conference call, the Individual Defendants expressed an unwillingness to make head-to-head comparisons between the 302 and 313 studies, to compare and contrast efficacy results by patient subgroup between the individual studies or as pooled results from both studies. Defendant Jackson answered the following question asked by Greg Wade, an analyst for Pacific Growth Equities:

[Wade:] OK. And if you've had a chance to do sort of pooled analysis between the two completed studies, do you - do you start to reach a level of statistical significance on these endpoints?

[Jackson:] Too early, I think, Greg, to start to talk about the pooled analysis until we pull together the data with 308 for the integrated summary of efficacy in the NDA.

- 56. If curiosity was not enough to cause defendants to inquire, the statistical analysis plan for the EnteregTM clinical program had prespecified the analysis of results for the different patient subgroups amongst the studies. Defendant Jackson knew that *the only reason to delay* making a pooled comparison between the 302 and 313 studies was to impede an understanding of how the therapy worked in the different patient subgroups. However, *there was ample reason to avoid discussion of pooled results between these two studies*, since this would have forced defendant Jackson to acknowledge the fact that the differences in patient response between the subgroups had impacted the results of the studies.
- 57. During the conference call on September 23, 2003, defendant Jackson also attempted to explain the differences in dropout rates between the 302 and 313 studies to Scott Bruenstein, an analyst for J.P. Morgan Assets:

[Jackson:] Yes, I think, Scott, good morning - what you are getting at was the lower dropout rate in the 12 milligram [which was] really noticeable in this study compared to the placebo group. Yes. I think, if we go back to the April conference, when we were talking about the results in the 12 milligram in the 302 study, we did talk about the fact that we found no other qualitative or other differences to explain the *bad luck*, I guess. In 302, we got so many that dropped out. There was no concern about the tolerability of the 12 milligrams.

That's why we increased the power of enrollment in this study and what we've seen is really no difference between six and 12 milligrams in terms of the adverse events for which patients drop out or the actual dropout rate.

[Bruenstein:] And what was, actually, the dropout rate? I just missed that in the slides.

[Jackson:] In 313, it was 8.5% in the 12-milligram group, compared with - for adverse events - compared with 17.8% in the 302 study.

- 58. Defendant Jackson stated that "bad luck" caused the differences in the patient dropout rates between the 302 and 313 studies, in order to conceal the fact that the *differences in patient response between the subgroups* was the real reason for the different dropout rates in the studies. Defendant Jackson knew that by breaking down the study results and dropout rates by patient subgroup, he would have to concede that these differences had impacted the results between the two studies, including differences in the dropout rates.
- 59. Yet another attempt was made during the September 23, 2003 conference call to engage defendants about the impact of the different patient subgroups on the Phase III studies. This time, Jim Birchenoff, an analyst with Lehman Brothers, addressed the issue directly by raising concerns about the confounding impact of the simple hysterectomy patient subgroup on the studies:

[Birchenoff:] OK. And then, just one final question - just thinking about filing and dose, do you think you're going to need a confirmatory study at 12 milligrams to file at that dose. And if so, do you have concerns about the confounding impact of simple hysterectomies in any other trial?

[Peacock:] Well, I'm not sure there's a confounding impact. The simple hysterectomies in the other trial, I think, you know, we haven't spoken about the information from study 302, broken out by the patient types. What we have seen in prior studies is clearly the duration of ileus in the simple hysterectomy patient is shorter than in the patient that's undergoing bowel resection surgery. However, as we've indicated before, there are patients who undergo a simple hysterectomy who go into an extended ileus. You can't predict up front who they're going to be. And so, we believe there's potential utility for Alvimopan there. In terms of picking the dose, again, I have to go back and say you really need to get all of the data pulled together and then sit down and make an intelligent choice about that.

60. Defendant Peacock's carefully crafted response regarding the potential utility of alvimopan in treating simple hysterectomy patients during the September 23, 2003 conference call was false and misleading for the following reasons: (i) the National Institutes of Health reports that

hospital stays for bowel resection surgery are in the range of five to seven days; (ii) the American Cancer Society reports that hospital stays for simple hysterectomies are, in comparison, relatively short, in the range of one to two days for vaginal procedures and three to five days for abdominal procedures, versus radical hysterectomies requiring hospital stays in the range of five to seven days; (iii) comparing only the cumulative percentages in all studies for placebo versus alvimopan treated patients discharged on postoperative days two, four and seven for the 313 or 302 studies, it remained difficult to conclude that 6 mg or 12 mg alvimopan would demonstrably shorten the length of a hospital stay for short stay patients; and (iv) since the Company intended to again include up to 20% simple hysterectomy patients in prospective study 308, common sense dictated that these patients could confound study results.

- 61. In the slides posted to the Company Web site on September 23, 2003, the Company reported a mean difference for length of hospital stay between drug and placebo-treated patients of 13 hours for the 6 mg dose and 20 hours for the 12 mg dose. However, these "mean differences" hide the dubious value of alvimopan therapy on patients requiring a short hospital stay. It is true that defendant Peacock admitted during the September 23, 2003 conference call that the duration of ileus in simple hysterectomy patients was shorter than for patients undergoing bowel surgery. However, when defendant Peacock stated "there are patients who undergo a simple hysterectomy who go into an extended ileus. You can't predict up front who they're going to be," he stated a fact, but did so to mislead Jim Birchenoff, who was interested specifically in the *confounding impact of the typical simple hysterectomy patient* on the trials. Defendant Peacock concealed his knowledge of the fact that patients requiring shorter hospital stays, such as the typical simple hysterectomy patient, could negatively impact the outcome of the alvimopan clinical trials.
- 62. With the exception of the failed 12 mg alvimopan arm in study 302, each and every one of the studies at the 6 mg and 12 mg dosage levels demonstrated that the difference in the cumulative percentage of hospital discharge orders for alvimopan versus placebo treated patients was disproportionately higher for patients requiring longer hospital stays. Only by calculating the

cumulative percentage of discharge orders by day can one observe this phenomena, as is produced here, based on the bar chart data found on pages 12 and 13 of the September 23, 2003 data presentation, posted by defendants on their Web site, shown here as Table 1.

Table 1

Post Operative Day		cebo Cumulative %	6 mg	ets Discharged Alvimopan at Cumulative		g Alvimopan ent Cumulative %
2	0.9	0.9	0.9	0.9	2.6	2.6
3	7.4	8.3	11.5	12.4	8.0	10.6
4	23.1	31.5	19.8	32.2	25.3	35.9
5	21.8	53.3	24.5	56.7	25.8	61.7
6	12.7	66.0	14.8	71.5	18.7	80.4
7	6.7	72.7	10.4	81.9	8.4	88.8
8	5.3	78.0	8.9	90.8	1.2	90.0
9	2.1	80.1	1.4	92.2	3.0	93.3
10	5.1	85.2	0.0	92.2	1.5	93.7
11+	14.8	100.0	7.8	100.0	6.3	100.0

- Consider, for example, the statement of the Individual Defendants in the September 23, 2003 data presentation for the 313 study, that the mean difference for length of hospital stay between drug and placebo-treated patients was 13 hours for the 6 mg dose and 20 hours for the 12 mg dose. Looking at the day 7 data in Table 1 above, the percentage of total subjects released at the 6 mg and 12 mg levels were ahead of placebo by 9.2% and 16.1%, respectively. In comparison with the highly positive results observed by day 7, the percentage of total subjects released at the 6 mg and 12 mg levels by day 4 were ahead of placebo by only 0.7% and 4.4%, respectively. And, finally, in comparison with results observed by day 4, the percentage of total subjects released at the 6 mg and 12 mg levels by day 2 were ahead of placebo by *zero percent* and 1.7%, respectively.
- 64. A similar analysis of the data for study 302, based on the charts found on pages 10 and 15 of the April 2, 2003 data presentation for study 302, posted by defendants on their Web site, is also possible. Other approaches for review of this hospital discharge data are possible. However, despite the fact that the defendants concealed the breakdown of results by patient subgroups, it is still

clear, from this limited comparison, that patients requiring a longer hospital stay receive a disproportionately greater benefit from alvimopan, relative to those requiring a shorter hospital stay. Since simple hysterectomy patients typically require the shortest range in days for a hospital stay, it was wholly unreasonable for the defendants to attempt to dismiss the confounding impact this patient subgroup would have on the clinical program, or to conceal a breakdown of the available data by patient subgroup.

- 65. In all, each and every one of the Individual Defendants' false, misleading and evasive explanations during the September 23, 2003 conference call served to allay concerns within the investment community about the inadequacies of the existing data or the potential problems, going forward, with the 308 study. Defendants' scheme worked and the Company's press release and contemporaneous conference call of September 23, 2003 sent the Company's shares soaring above \$19 per share an increase of nearly 33%.
- 66. With the Company's shares trading at inflated levels, the Individual Defendants sought to, and did, take advantage of the "inflation."
- 67. On November 12, 2003, the Individual Defendants caused the Company to issue a press release entitled "Adolor Corporation Announces Closing of Equity Offering." Through the offering the Company raised \$119 million in gross proceeds. The press release stated in relevant part:

Adolor Corporation today announced that it has completed the sale of 6,900,000 shares of common stock at a public offering price of \$17.25 per share. This amount includes the exercise of the underwriters' option to purchase 900,000 shares to cover overallotment. The gross proceeds from the offering were approximately \$119 million. Merrill Lynch & Co. acted as the lead underwriter in this offering. Lehman Brothers Inc., Pacific Growth Equities, LLC, Adams, Harkness & Hill, Inc. and First Albany Corporation acted as co-managers.

68. On January 13, 2004, the Individual Defendants caused the Company to issue a press release entitled "Adolor Corporation Announces Top-Line Results in Entereg™ Phase 3 Clinical Study 308 in Postoperative Ileus; - NDA Submission Targeted Late First Half 2004." The press release stated in relevant part:

Adolor Corporation announced today top-line results of its Phase 3 clinical study (14CL308) of EnteregTM (alvimopan) in the management of postoperative ileus (POI). Study 14CL308 enrolled 666 subjects who were scheduled to undergo large or small bowel resections, or simple or radical hysterectomy.

In the primary endpoint of Study 14CL308, time to recovery of gastrointestinal function, a positive trend was observed when each of the EnteregTM 6 mg and 12 mg treatment groups was compared to the placebo group (Cox proportional hazard model: for 6 mg group, hazard ratio = 1.20, P = 0.079; for 12 mg group, hazard ratio = 1.24, P = 0.038).

A difference in favor of EnteregTM was observed for all of the secondary endpoints in both the 6 mg and 12 mg treatment groups. Statistically significant differences were achieved in time to hospital discharge order written in each of the 6 mg and 12 mg treatment groups as compared to the placebo group.

"We are pleased today to report results from Study 308," stated Bruce A. Peacock, president and chief executive officer of Adolor. "Our four Phase 3 clinical trials enrolled more than 2,000 subjects, which we believe represents a very substantial clinical development program. The completion of Study 308 supports our goal of submission of a New Drug Application for EnteregTM late in the first half of 2004."

Mean times to recovery of gastrointestinal function were approximately 8 hours and 10 hours sooner for each of the EnteregTM 6 mg and 12 mg treatment groups, respectively, as compared with the placebo group. Mean times to hospital discharge order written were approximately 14 and 15 hours sooner for each of the 6 mg and 12 mg treatment groups, respectively, as compared with the placebo group. For the approximately 437 subject subgroup of bowel resection subjects, mean times to hospital discharge order written were approximately 17 hours and 21 hours sooner for the 6 mg and 12 mg treatment groups, respectively, each as compared to the placebo group.

EnteregTM was generally well tolerated in this study. The most frequently observed adverse events in both the 6 mg and 12 mg treatment groups and the placebo groups were nausea, vomiting, and pruritus.

69. The January 13, 2004 press release pointed to the shocking failure of the 308 study, the third in the series of Phase III clinical trials for the NDA submission, to achieve statistically significant results against the primary endpoint, not only at the 12 mg dosage level, but at the 6 mg dosage level as well. As defendants indicated during the September 23, 2003 conference call, the patient subgroups studied at in the 308 trial were similar to those looked at in the 302 trial, since both studies looked at simple hysterectomy patients. Since simple hysterectomy patients were included to the 308 trial, it was, in fact, dissimilar to study 313.

70. By this time, the facts about the different patient response by subgroup, the stark differences between the study results and the different patient populations between the studies were not lost on the analysts. Eric Endy, an analyst for Merrill Lynch asked the following questions about the outcome of the EnteregTM Phase III program, particularly the analysis of results by the individual patient subgroups and the impact of additional clinical trials on the timeline for approval:

[Endy:] How long on average did the prior studies take from start of enrollment until completion, until data was released?

[Peacock:] Until data was released? I don't want to give you a wrong answer off the top of my head, sorry.

[Endy:] do you have a round number?

[Peacock:] I would say, I guess you're looking at somewhere in a year's time period David, is that right?

[Jackson:] Yes, a little bit north of that Bruce. Probably closer to 21 months.

[Endy:] Twenty-one months.

[Jackson:] Could I just add a comment here.

[Endy:] Yes, sure.

[Jackson:] Look at that total package. If the agency were to want to look at that group, there's more than a thousand patients with bowel resection there. That's a lot.

[Endy:] I guess the issue [is] that it's not a perspectively defined sub group analysis, and I know the FDA is not very fond of that.

[Peacock:] Yes, just to clarify that, it is a perspectively defined sub group analysis, it's not a perspectively defined sub group for purposes of primary analysis. But it's not as though we went and posted] the data, and said, let's call that a sub group. Our SAP, we say up front, that's a sub group we're going to look at. But again, I also want to be clear to say that it was not a predefined sub group for the purposes of primary analysis. But it is a predefined sub group.

71. On January 14, 2004, as a result of the shocking news about the failed 308 study and its impact on the phase III clinical program for EnteregTM, the price of Adolor's stock took a nosedive, falling 37% to close at \$13.73 per share, on unprecedented volume of 12.7 million shares.

REASONS THE STATEMENTS WERE IMPROPER

- 72. The true facts, which were known by each of the defendants but concealed from the investing public during the Relevant Period were as follows:
- (a) The clinical trial failure in the Entereg Phase III 302 study for postoperative ileus was directly related to objective failure of the therapy in certain patient subgroups, particularly those patients treated for simple hysterectomy;
- (b) Additional Entereg[™] Phase III clinical trials composed of patient subgroups similar to the 302 study would risk repetition of the same therapy failures;
- (c) The 302 study failure at the 12 mg dosage was due to therapy failures in certain patient subgroups, particularly those patients treated for simple hysterectomy, and not "limited power" or insufficient numbers of patients in the study;
- (d) Despite representations to the contrary, defendants were in a position to make meaningful comparisons for the data and results between patient subgroups, for the 302 and 313 studies, from the very beginning of the Relevant Period;
- (e) Despite defendants' expressions of disbelief at suggestions by analysts that distinctly different results for certain patient subgroups had somehow impacted the quality of results for the 302 and 313 clinical studies, defendants were fully aware of these differences and that the clinical program was indeed adversely impacted, from the very beginning of the Relevant Period;
- (f) The Entereg[™] Phase III 313 clinical study met the primary efficacy endpoint, at both dosage levels, because it *excluded* certain patient subgroups already known by defendants prior to the Relevant Period to produce disappointing results for the treatment of postoperative ileus;
- (g) The Entereg[™] Phase III 308 prospective study was at great risk of failing to achieve statistically significant results for the primary efficacy endpoint, at both dosage levels, because it would include a large number of certain patient subgroups already known to produce disappointing results for the treatment of postoperative ileus;

- (h) Elimination of certain patient subgroups already known to produce disappointing results for the postoperative ileus indication from the 313 study created an opportunity to present highly encouraging clinical results to the investment community at the very beginning of the Relevant Period, while deferring the prospect of disappointing results from the prospective 308 study; and
- (i) Since the Entereg[™] Phase III pivotal studies were designed to study two different dosages across a number of patient subgroups in three separate trials, defendants were aware, from the very beginning of the Relevant Period, that the mixed results within the patient subgroups for the 302 and 313 studies confounded the results, making it difficult for the FDA to approve an Entereg[™] NDA based on the prospect of disappointing results from the prospective 308 study.

ILLEGAL INSIDER SELLING

72. While in possession of the undisclosed material adverse information, the Insider Selling Defendant sold the following shares of Adolor stock:

Name	Position	Date	Shares	Price	Proceeds
Robert T. Nelsen	D	12/8/2003	22.000	\$ 19.11	\$420.420.00

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

73. Plaintiff brings this action derivatively in the right and for the benefit of Adolor to redress injuries suffered, and to be suffered, by Adolor as a direct result of the breaches of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment, as well as the aiding and abetting thereof, by the Individual Defendants. Adolor is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

- 74. Plaintiff will adequately and fairly represent the interests of Adolor in enforcing and prosecuting its rights.
- 75. Plaintiff is and was an owner of the stock of Adolor during times relevant to the Individual Defendants' wrongful course of conduct alleged herein, and remains a shareholder of the Company.
- 76. The current Board of Adolor consists of eight individuals: defendants Goddard, Nash, Nickelson, Anido, Hager, Peacock, Madden and Nelsen. Plaintiff has not made any demand on the present Board to institute this action because such a demand would be a futile, wasteful and useless act, particularly for the following reasons:
- (a) As a result of their access to and review of internal corporate documents; conversations and connections with other corporate officers, employees and directors; and attendance at management and Board meetings, each of the defendants knew the adverse non-public information regarding the improper accounting. While in possession of this material adverse non-public information regarding the Company, the following current members of the Adolor Board participated in the illegal insider selling:
- (i) During the Relevant Period, Nelsen sold 22,000 shares of Adolor stock for proceeds of \$420,420. Because this defendant received a personal financial benefit from the challenged insider trading transactions, this defendant is interested and any demand upon him is futile;
- (b) The Compensation Committee of the Board determines the executive annual salary, bonus and stock ownership programs. The Compensation Committee annually evaluates performance of, and determines and reports to the full Board the compensation of, the CEO and other

executive officers, based upon a combination of the achievement of corporate goals and individual performance. The Compensation Committee is comprised of defendants Anido, Nash and Nelsen. As the members of the Compensation Committee singularly control the other defendants' awards, the remaining members of the Board will not institute this action against defendants Anido, Nash and Nelsen. To do so would jeopardize each defendant's personal financial compensation. Thus, demand on defendants Nickelson, Hager, Peacock, Madden and Goddard is futile;

- with Adolor, pursuant to which he received and continues to receive substantial monetary compensations and other benefits. Specifically, for FY:03, Adolor paid defendant Peacock \$536,202, in salary, bonus and other compensation, and granted him 150,000 options to purchase Adolor stock. Accordingly, defendant Peacock lacks independence from defendants Anido, Nash and Nelsen, defendants who are not disinterested and/or independent and who exert influence over defendant Peacock's compensation by virtue of his position as CEO and President. This lack of independence renders defendant Peacock incapable of impartially considering a demand to commence and vigorously prosecute this action;
- (d) According to Adolor's Proxy Statement filed with the SEC on or about March 31, 2004, defendants Madden, Hager, Nickelson were, during the Relevant Period, members of the Audit Committee. The Audit Committee is responsible for assisting the Board in monitoring the integrity of the financial statements of the company, the Company's compliance with legal and regulatory requirements related to the financial statements including the Company's systems of internal controls regarding finance, accounting, legal compliance and ethics that have been established relating to such financial statements, and the independence and performance of the

Company's external auditors. Nonetheless, the Audit Committee recommended that the Board include the improper financial statements in Adolor's Annual Report on Form 10-K for the year ended December 31, 2003 as filed with the SEC. By such actions, defendants Madden, Hager and Nickelson breached their duties by causing or allowing the improper financials described above. As a result of these defendants' breach of their duties, any demand upon them is futile;

- (e) The entire Adolor Board and senior management participated in the wrongs complained of herein. Adolor's directors are not disinterested or independent due to the following: defendants Goddard, Peacock, Anido, Madden, Hager, Nickelson, Nash and Nelsen served on the Adolor Board during the Relevant Period. Pursuant to their specific duties as Board members, each was charged with the management of the Company and to conduct its business affairs. Each of the above-referenced defendants breached the fiduciary duties that they owed to Adolor and its shareholders in that they failed to prevent and correct the improper financials. Thus, the Adolor Board cannot exercise independent objective judgment in deciding whether to bring this action or whether to vigorously prosecute this action because its members are interested personally in the outcome as it is their actions that have subjected Adolor to millions of dollars in liability for possible violations of applicable securities laws;
- (f) Defendants Goddard, Nash, Nickelson, Anido, Hager, Madden and Nelsen are eligible to receive options to purchase Common Stock awarded under Adolor's Amended and Restated 1994 Equity Compensation Plan and Adolor's 2003 Stock-Based Incentive Compensation Plan. In fiscal 2003, defendants Goddard, Nash, Nickelson, Anido, Hager, Madden and Nelsen were granted stock options to purchase 13,000 shares of Adolor Common Stock on the date of Adolor's 2003 annual meeting at a per share exercise price equal to the fair market value of Adolor Common

Stock on that date. These stock options will vest on the first anniversary of the grant. In fiscal 2004, defendants Goddard, Nash, Nickelson, Anido, Hager, Madden and Nelsen will be granted stock options to purchase 15,000 shares of Adolor Common Stock on the date of Adolor's 2004 annual meeting at a per share exercise price equal to the fair market value of Adolor Common Stock on that date. In addition, defendants Goddard, Nash, Nickelson, Anido, Hager, Madden and Nelsen will receive an option to purchase 15,000 shares of Adolor Common Stock upon his or her initial election to the Board at a per share exercise price equal to the fair market value of Adolor Common Stock on that date, and the shares of Common Stock underlying those options will vest in three equal annual installments on the anniversary of the grant. Because of these lucrative stock options, any demand on defendants Goddard, Nash, Nickelson, Anido, Hager, Madden and Nelsen will be futile;

- (g) The Individual Defendants, because of their inter-related business, professional and personal relationships, have developed debilitating conflicts of interest that prevent the Board members of the Company from taking the necessary and proper action on behalf of the Company as requested herein. In addition to the conflicts that exist as a result of their participation in the improper accounting and insider selling, as detailed herein *supra*, the majority of the Board, including the defendants listed below, are subject to the following prejudicial entanglements:
 - (i) In July 2003, the Company entered into a consulting agreement with defendant Goddard. The agreement provides that defendant Goddard will provide strategic business advice and related assistance to the CEO and management team in the role of an advisor. Defendant Goddard will receive quarterly compensation of \$8,500 and a stock option grant under the 2003 Plan at fair market value to purchase 4,000 shares of our Common Stock. In August 2002, the Company entered into an agreement with ViroPharma Incorporated ("ViroPharma") under which ViroPharma provided clinical trial analysis, data management and report writing services for a total of five EnteregTM Phase 1 clinical studies. The total cost to the Company for the services was \$357,000. Defendant Nash, was the Chairman of the Board of Directors of ViroPharma at the time the agreement was entered into.

Defendant Madden, was a director of Royalty Pharma AG, a private investment management firm specializing in the acquisition of royalty interests in pharmaceutical products, until March, 2004. Adolor license's from Eli Lilly and Company, through an assignment from Roberts Laboratories Inc., the compound that is the basis of Adolor's lead product candidate, EnteregTM. Under that license agreement, Adolor is required to pay certain royalties to Eli Lilly based on product sales. In March 2002, Eli Lilly sold the right to receive a portion of those royalties to Royalty Pharma. In connection with the public offering of 6,900,000 shares of Adolor Common Stock in November 2003, the Company requested the underwriters of that offering to reserve for sale 60,000 shares of our Common Stock offered to defendant Madden at the public offering price. The number of shares available to the general public in the offering was reduced by the number of reserved shares that defendant Madden purchased. Because of these entangling financial relationships, defendants Goddard, Nash and Madden will not take any action that may jeopardize their lucrative income

- (h) The Director Defendants of Adolor, as more fully detailed herein, participated in, approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from Adolor's stockholders or recklessly and/or negligently disregarded the wrongs complained of herein, and are therefore not disinterested parties;
- (i) In order to bring this suit, all of the directors of Adolor would be forced to sue themselves and persons with whom they have extensive business and personal entanglements, which they will not do, thereby excusing demand;
- (j) The acts complained of constitute violations of the fiduciary duties owed by Adolor's officers and directors and these acts are incapable of ratification;
- (k) Each of the Director Defendants of Adolor authorized and/or permitted the false statements disseminated directly to the public or made directly to securities analysts and which were made available and distributed to shareholders, authorized and/or permitted the issuance of various of the false and misleading statements and are principal beneficiaries of the wrongdoing alleged herein, and thus could not fairly and fully prosecute such a suit even if such suit was

instituted by them;

- (l) Any suit by the current directors of Adolor to remedy these wrongs would likely expose the Individual Defendants and Adolor to further violations of the securities laws that would result in civil actions being filed against one or more of the Individual Defendants, thus, they are hopelessly conflicted in making any supposedly independent determination whether to sue themselves;
- (m) Adolor has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Individual Defendants and current Board have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Adolor any part of the damages Adolor suffered and will suffer thereby;
- (n) If the current directors were to bring this derivative action against themselves, they would thereby expose their own misconduct, which underlies allegations against them contained in class action complaints for violations of securities law, which admissions would impair their defense of the class actions and greatly increase the probability of their personal liability in the class actions, in an amount likely to be in excess of any insurance coverage available to the Individual Defendants. In essence, they would be forced to take positions contrary to the defenses they will likely assert in the securities class actions. This they will not do. Thus, demand is futile; and
- (o) If Adolor's current and past officers and directors are protected against personal liability for their acts of mismanagement, abuse of control and breach of fiduciary duty alleged in this Complaint by directors' and officers' liability insurance, they caused the Company to purchase that insurance for their protection with corporate funds, *i.e.*, monies belonging to the stockholders of Adolor. However, due to certain changes in the language of directors' and officers'

liability insurance policies in the past few years, the directors' and officers' liability insurance policies covering the defendants in this case contain provisions that eliminate coverage for any action brought directly by Adolor against these defendants, known as, *inter alia*, the "insured versus insured exclusion." As a result, if these directors were to sue themselves or certain of the officers of Adolor, there would be no directors' and officers' insurance protection and thus, this is a further reason why they will not bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage exists and will provide a basis for the Company to effectuate recovery. If there is no directors' and officers' liability insurance at all then the current directors will not cause Adolor to sue them, since they will face a large uninsured liability.

77. Moreover, despite the Individual Defendants having knowledge of the claims and causes of action raised by plaintiff, the current Board has failed and refused to seek to recover for Adolor for any of the wrongdoing alleged by plaintiff herein.

COUNT ONE

Against the Insider Selling Defendant for Breach of Fiduciary Duties for Insider Selling and Misappropriation of Information

- 78. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth. At the time of the stock sales set forth herein, the Insider Selling Defendant knew the information described above, and sold Adolor common stock on the basis of such information.
- 79. At the time of the stock sales forth herein, the Insider Selling Defendant knew the information described above, and sold Adolor common stock on the basis of such information.
 - 80. The information described above was proprietary non-public information concerning

the Company's financial condition and future business prospects. It was a proprietary asset belonging to the Company, which the Insider Selling Defendant used for their own benefit when they sold Adolor common stock.

- 81. At the time of their stock sales, the Insider Selling Defendant knew that the Company's revenues were materially overstated. The Insider Selling Defendant's sales of Adolor common stock while in possession and control of this material adverse non-public information was a breach of their fiduciary duties of loyalty and good faith.
- 82. Since the use of the Company's proprietary information for their own gain constitutes a breach of the Insider Selling Defendant's fiduciary duties, the Company is entitled to the imposition of a constructive trust on any profits the Insider Selling Defendant obtained thereby.

COUNT TWO

Against All Defendants for Breach of Fiduciary Duty

- 83. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 84. The Individual Defendants owed and owe Adolor fiduciary obligations. By reason of their fiduciary relationships, the Officer Defendants and Director Defendants owed and owe Adolor the highest obligation of good faith, fair dealing, loyalty and due care.
- 85. The Individual Defendants, and each of them, violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, oversight, good faith and supervision.
- 86. Each of the Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly misrepresent the financial results of the Company and failed to correct the Company's publicly reported financial results and guidance. These actions could not have

been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

- 87. As a direct and proximate result of the Individual Defendants' failure to perform their fiduciary obligations, Adolor has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.
 - 88. Plaintiff on behalf of Adolor has no adequate remedy at law.

COUNT THREE

Against All Defendants for Abuse of Control

- 89. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 90. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Adolor, for which they are legally responsible.
- 91. As a direct and proximate result of the Individual Defendants' abuse of control, Adolor has sustained significant damages.
- 92. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.
 - 93. Plaintiff on behalf of Adolor has no adequate remedy at law.

COUNT FOUR

Against All Defendants for Gross Mismanagement

94. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

- 95. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Adolor in a manner consistent with the operations of a publicly held corporation.
- 96. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Adolor has sustained significant damages in excess of hundreds of millions of dollars.
- 97. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.
 - 98. Plaintiff on behalf of Adolor has no adequate remedy at law.

COUNT FIVE

Against All Defendants for Waste of Corporate Assets

- 99. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 100. As a result of the improper accounting, and by failing to properly consider the interests of the Company and its public shareholders by failing to conduct proper supervision, defendants have caused Adolor to waste valuable corporate assets by paying incentive based bonuses to certain of its executive officers and incur potentially millions/billions of dollars of legal liability and/or legal costs to defend defendants' unlawful actions.
- 101. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.
 - 102. Plaintiff on behalf of Adolor has no adequate remedy at law.

COUNT SIX

Against All Defendants for Unjust Enrichment

- 103. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.
- 104. By their wrongful acts and omissions, defendants were unjustly enriched at the expense of and to the detriment of Adolor.
- 105. Plaintiff, as a shareholder and representative of Adolor, seeks restitution from these defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

PRAYER FOR RELIEF

WHEREFORE, plaintiff demands judgment as follows:

- A. Against all of the Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment;
- B. Extraordinary equitable and/or injunctive relief as permitted by law, equity and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of Adolor has an effective remedy;
- C. Awarding to Adolor restitution from the defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the defendants;

- D. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
 - E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: August 2, 2004

LAW OFFICES BERNARD M. GROSS P.C. BY:

/s/ Deborah R. Gross

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